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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,904

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Robert R Redfield

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EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,904	Applicant(s) REDFIELD ET AL.	
	Examiner KENDRA D. CARTER	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,10-12,15-20,23,25-30,33,35 and 37-47 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15-20, 23, 25-30, 33, 35 and 37-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7 and 10 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/12/05;4/14/08;4/21/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 3, 5-7 and 10 in the reply filed on April 20, 2009 is acknowledged. The Applicant's also elected rapamycin as the G1 phase arresting agent and TAK 779 as the antiviral agent, which effect the claims in Group I. The traversal is on the ground(s) that Groups I – VIII are one invention and do not possess sufficient differences to warrant issuance of separate patents. Further, the cost of filing separate applications would be a burden. This is not found persuasive because the inventions of each group are different. For instance the method of Group VIII is drawn to reduce an effective dosage of an HIV antiviral agent, whereas the method of Group VII is drawn to preventing HIV infection. Nevertheless, the special technical feature has been taught by Long et al. as discussed in the previous office action.

Claims 1, 5, 6, 7, 10, 15-18, 25-27, 33, 37 and 41 are amended and claims 2, 4, 8, 9, 13, 14, 21, 22, 24, 31, 32, 34, 36 and 48-54 are cancelled. Claims 11, 12, 15-20, 23, 25-30, 33, 35 and 37-47 are withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 and 10 are drawn to the use of a composition for increasing concentrations of chemokines to reduce entry of HIV virus into mononuclear cells through binding of chemokine binding receptors and whereing the composition is administered in a cyclic therapy program. The intended use does not get patentable weight in composition claims. The claims are only treated on the merits as related to a composition.

Claim Objections

Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Particularly, claim 10 is dependent on claim 2, which is cancelled. For compact prosecution, the Examiner examined the claim based on dependency on claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1, 3, 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock (US 2002/0018776 A1) in view of Baba et al. (Proc. Natl. Acad. Sci. USA, May 1999, vol. 96, pp. 5698-5703).

Hancock teach a method for inhibiting the rejection of transplanted grafts comprising an effective amount of an antagonist of CCR5 and an effective amount of an immunosuppressive agent (see abstract and claims 1, 6 and 13). Immunosuppressive agents include rapamycin (see paragraph 60; addresses claims 1 and 3). The composition can be administered orally, parenterally, rectally, nasally or topically (see paragraph 70; addresses claim 7). The drugs can be taken at the same time (see paragraph 67). An effective amount of the drugs is the amount sufficient to achieve a desired therapeutic effect (see paragraph 68; addresses claim 1).

Hancock does not teach TAK 779 (claims 1, 5 and 6).

Baba et al. teaches that TAK-779 is a small-molecule, nonpeptide that is a specific CCR5 antagonist (see title and abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the compositions of Hancock et al. and TAK 779 because TAK 779 is a small molecule that specifically antagonizes CCR5.

In regards to the effective amount of the G1 phase arresting compound sufficient enough to increase concentrations of extracellular beta-chemokines, Hancock teaches this limitation because the effective amount of the drugs is the amount sufficient to achieve a desired therapeutic effect (see paragraph 68). Thus, it is within the skill of the art to determine the effective amount to obtain the desired therapeutic effect.

The composition of claim 1 is obviously taught by Hancock in view of Baba et al., thus claim 10 is taught.

2) Claims 1, 3, 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vezina (WO 94/05300) in view of Baba et al. (Proc. Natl. Acad. Sci. USA, May 1999, vol. 96, pp. 5698-5703).

Vezina teach methods and compositions for treating the pregression of an HIV infection comprising administering rapamycin and another anti-HIV agent (see abstract and claims 1 and 3; addresses claims 1 and 3). The compositions can be administered orally or parenterally (see claims 7 and 8; addresses claim 7).

Vezina does not teach TAK 779 (claims 1, 5 and 6).

Baba et al. teaches that TAK-779 is a small-molecule, nonpeptide that is a specific CCR5 antagonist with highly potent and selective anti-HIV-1 activity (see title and abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the compositions of Vezina and TAK 779 because TAK 779 is a specific CCR5 antagonist with highly potent and selective anti-HIV-1 activity. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

In regards to the effective amount of the G1 phase arresting compound sufficient enough to increase concentrations of extracellular beta-chemokines, it is within the skill of the art to determine the effective amount to obtain the desired therapeutic effect.

The composition of claim 1 is obviously taught by Vezina in view of Baba et al., thus claim 10 is taught.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617